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09/973,945	10/11/2001	Susheng Gan	50229-287	5823

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MCDERMOTT WILL & EMERY LLP  
600 13TH STREET, N.W.  
WASHINGTON, DC 20005-3096

EXAMINER

LY, CHEYNE D

ART UNIT PAPER NUMBER

1631

DATE MAILED: 03/31/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/973,945

Applicant(s)

GAN ET AL.

Examiner

Cheyne D. Ly

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 24 January 2005.
- 2a) ☐ This action is **FINAL**.                      2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 1-11 are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

### **DETAILED ACTION**

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on January 24, 2005 has been entered.
2. Claims 1-11, SEQ ID NO. 9, are examined on the merits.

### **OBJECTIONS**

3. Claim 2 is objected to due to the inclusion of subject matter, which has been non-elected due to a restriction requirement and therefore, the non-elected subject matter has been withdrawn from consideration.

### **RESPONSE TO ARGUMENT**

4. Applicant argues that the included non-elected subject matter in claim 2 is merely the complements or variants of SEQ ID NO:9. Applicant's argument has been fully considered and found to be unpersuasive because sequences that are complements or variants of SEQ ID NO:9 could reasonably be construed as being patentably distinct from the sequence of SEQ ID NO:9. It is noted that only those sequences which are patentably indistinct from the selected sequences are examined together. Further, Applicant's request to have a reasonably number of nucleotide sequences examined in view of the amended claims has been considered and denied. Due to the number of these requests made, it is practically impossible to accommodate all requests. The overwhelming number of sequences poses undue search burden when more than one nucleic acid

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sequence is elected, thus making the previous waiver to a complete search of all of the sequences of this instant application, effectively impossible to reasonably implement.

**CLAIM REJECTIONS - 35 U.S.C. § 112, SECOND PARAGRAPH**

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

7. Claim 1, (a), recites the limitation of “at least one copy of a polynucleotide” which causes said claim to be vague and indefinite because the metes and bounds of said limitation has not been defined. For example, the instant specification discloses “an isolated polynucleotide that contains at least one copy of either a polynucleotide region having the sequence set forth in SEQ ID NO:9...or a polynucleotide region having a sequence that is a variant or fragment of the sequence set forth in SEQ ID NO:9” (page 2, [07]). Therefore, claim 1 is not clear whether “one copy” is directed to the sequence set forth in SEQ ID NO:9, or a variant or fragment of the sequence set forth in SEQ ID NO:9. Clarification of the metes and bounds is required. The same issue is present in claim 11. Claims 2-10 are rejected for being dependent from claim 1.

8. Claim 1, (b), recites the limitation of “the complement” which causes said claim to be vague and indefinite because the metes and bounds of said limitation has not been defined. For

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example, the instant specification discloses the “term ‘complementary’ applies to nucleic acid...is complementary to all or a portion of a reference polynucleotide sequence” (page 5, [20]). Therefore, claim 1 is not clear whether “the complement” is directed “to all or a portion of a reference polynucleotide sequence” of SEQ ID NO:9. Clarification of the metes and bounds is required. The same issue is present in claim 11. Claims 2-10 are rejected for being dependent from claim

### **LACK OF WRITTEN DESCRIPTION**

9. Claims 1-11 are rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

### **RESPONSE TO ARGUMENT**

10. Applicant argues that the claimed invention meets the written description requirement as defined by the Synopsis of Application of Written Description Guidelines published on the USPTO website. Applicant’s argument is not persuasive as discussed below.

11. Applicant points to Example 9 of the published Guidelines to assert that said Example supports that the claimed invention meets the Guidelines for written description. It is noted that Example 9 describes the highly stringent hybridization conditions as being 6XSSC and 65 degrees Celsius. While, the claimed invention recites “variant hybridizes...under 5XSSC and 42°C wash conditions” which is different from the stringent condition described in the

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Guidelines. Therefore, one of skill in the art would expect substantial variation among species encompassed within the scope of the claims because the conditions set forth in the claim would not yield structurally similar polynucleotides. Therefore, the pointed to Example does not support Applicant's argument.

12. Applicant's argument that the claims recite "a functional requirement where there is a relationship between structure and the relevant function" is not persuasive because Applicant has not defined with specificity as to what sequence is correlated with the plant genetic insulator activity. It is noted Applicant defines the term "insulator" and provides an exemplary insulator sequence such as the 16 bp sequence of SEQ ID NO. 9 (page 4, [16] and [17]). However, Applicant further discloses that the sequence of SEQ ID NO. 9, variant, or fragment of SEQ ID NO. comprises a region that has a genetic insulator activity (page 2, [07]). The disclosure is not specific as to what sequence of SEQ ID NO. 9 is responsible for the genetic insulator activity. Therefore, it is reasonable to assert that the specification does not disclose a representative number of species wherein one of skill in the art would conclude that Applicant was in possession of the claimed invention as commensurate with the scope of the claims.

#### **BASIS FOR REJECTION**

13. The specification discloses SEQ ID NO: SEQ ID NO. 9. Claims 1-11 are directed to encompass gene sequences having the sequence set forth in SEQ ID NO. 9, copy, variants, or complements of the polynucleotide set forth in SEQ ID NO. 9. With the exception of SEQ ID NO. 9, none of these sequences meet the written description provision of 35 USC 112, first

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paragraph. The specification provides insufficient written description to support the genus encompassed by the claim.

14. *Vas-Cath Inc. v. Mahurkar*, 19 USPQ2d 1111, makes clear that "applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention. The invention is, for purposes of the 'written description' inquiry, whatever is now claimed." (See page 1117.) The specification does not "clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed." (See *Vas-Cath* at page 1116.)

15. With the exception of SEQ ID NO: 9, the skilled artisan cannot envision the detailed chemical structure of the encompassed polynucleotides and/or proteins, regardless of the complexity or simplicity of the method of isolation. Adequate written description requires more than a mere statement that it is part of the invention and reference to a potential method for isolating it. See *Fiers v. Revel*, 25 USPQ2d 1601, 1606 (CAFC 1993) and *Amgen Inc. V. Chugai Pharmaceutical Co. Ltd.*, 18 USPQ2d 1016. In *Fiddes v. Baird*, 30 USPQ2d 1481, 1483, claims directed to mammalian FGF's were found unpatentable due to lack of written description for the broad class. The specification provided only the bovine sequence.

*University of California v. Eli Lilly and Co.*, 43 USPQ2d 1398, 1404, 1405 held that: "...To fulfill the written description requirement, a patent specification must describe an invention and do so in sufficient detail that one skilled in the art can clearly conclude that 'the inventor invented the claimed invention.'" *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (1997); *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989) (" [T]he description must clearly allow persons of ordinary skill in the art to recognize that [the inventor] invented what is claimed."). Thus, an applicant complies with the written description requirement "by

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describing the invention, with all its claimed limitations, not that which makes it obvious," and by using "such descriptive means as words, structures, figures, diagrams, formulas, etc., that set forth the claimed invention." *Lockwood*, 107 F.3d at 1572, 41 USPQ2d at 1966.

16. Therefore, only SEQ ID NO: 9 but not the full breadth of the claims 1-11 meet the written description provision of 35 USC 112, first paragraph. The species specifically disclosed are not representative of the genus because the genus is highly variant. Applicant is reminded that Vas-Cath makes clear that the written description provision of 35 USC 112 is severable from its enablement provision. (See page 1115.)

#### **CLAIM REJECTIONS - 35 USC § 102**

17. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

18. Claims 1-11 are rejected under 35 U.S.C. 102(b) as being clearly anticipated by Millar et al. (May 1999).

19. Due to the vague and indefinite issue directed to the limitation of "at least one copy", said limitation has been reasonably construed as a polynucleotide region having a sequence that is a variant or fragment of the sequence set forth in SEQ ID NO:9. Further, Miller et al. had been previously withdrawn, December 28, 2004, due to Applicant's argument, filed December 01, 2004, directed to the limitation of "having the sequence set forth in SEQ ID NO:9." Miller et al.



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is utilized in the instant rejection because of the vague and indefinite issues directed to the limitations of “at least copy” and “the complement” as discussed above.

20. Millar et al. discloses an isolated Arabiopsis polynucleotide (AF129511, positions 437-440) sequence having fragment set forth in SEQ ID NO. 9 (Figure 3), as in instant claims 1 and 11, (a), and claim 2.

21. It is noted that the wash conditions of the claimed invention has been reasonably interpreted as not stringent as discussed above. Further, the limitation of “the complement” is vague and indefinite as discussed above. Therefore, the polynucleotide of Millar et al. has been reasonably construed as capable of hybridizing to the complement (portion) of SEQ ID NO.9 under the claimed “wash conditions”, as in instant claims 1 and 11, (b).

22. The sequence of AF129511 is inserted into an expression vector and transformed into transgenic a plant or seed (page 835, column 1, Construction of the Transformation Vector and Generation of Transgenic Plants §), as in instant claims 3-10.

23. It is noted that the Millar et al. (May 1999) reference has been previously provided; therefore, said reference is not provided with the instant Office Action.

## CONCLUSION

24. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to (571) 272-0547. The USPTO's official fax number is (571) 273-8300.

25. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to confirm that the problem has been corrected. The USPTO's Patent Electronic Business Center is a complete service center supporting all patent business on the Internet. The USPTO's PAIR system provides Internet-based access to patent application status and history information. It also enables applicants to view the scanned images of their own application file folder(s) as well as general patent information available to the public.

26. For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

27. Any inquiry concerning this communication or earlier communications from the examiner should be directed to C. Dune Ly, whose telephone number is (571) 272-0716. The examiner can normally be reached on Monday-Friday from 8 A.M. to 4 P.M.

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28. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ardin Marschel, Ph.D., can be reached on (571) 272-0718.

C. Dune Ly  
3/25/05

*Ardin H. Marschel* 3/25/05  
ARDIN H. MARSCHEL  
PRIMARY EXAMINER